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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-------------------------|---------------------|------------------|
| 10/579,330 | 08/08/2006 | Minas Theodore Coronico | 37528-503N01US | 6478 |
| 64046 7590 02/17/2009 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C ONE FINANCIAL CENTER BOSTON, MA 02111 | | | | |
| EXAMINER WIEST, PHILIP R | | | | |
| ART UNIT 3761 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/579,330

Applicant(s)

CORONEO, MINAS THEODORE

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/09 has been entered.

Response to Amendment

2. In the reply filed 1/22/09, applicant amended claims 19 and 21. Claims 19-21 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 19 and 21 state that the ocular pressure spike comprises "a flexible fluid transfer tube formed of a biocompatible material, preferably biocompatible elastomeric material." The use of the word "preferably"

renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. (US 3,788,327) in view of L'Esperance (US 5,300,020). With respect to Claim 19, Donowitz discloses an ocular pressure spike shunt comprising a fluid transfer tube made from a biocompatible, substantially flexible material (Column 3, Lines 19-23). The tube has an inner (distal) end, an outer (proximal) end 34, a tubular lumen disposed therebetween, and a valve 48 for maintaining pressure in the eye at a normal level, said valve opens to permit fluid flow through the tube when a predetermined pressure is exceeded (Column 2, Line 65 through Column 3, Line 2). When implanted in the eye, the shunt is disposed such that the outer end is substantially flush with the outer surface of the cornea, and the inner end opens into the anterior chamber of the eye on the inner surface of the cornea. The implant is fully capable of being inserted into an ocular paracentesis incision port and removed from the eye after treatment is complete. See Figures 1, 2, and 4. Regarding claim 21,

Donowitz discloses the method of implanting an ocular shunt as described above, comprising forming an incision in the eye, and introducing the shunt (see rejection above) through the incision such that the outer end is flush with the surface of the cornea and the inner surface extends into the anterior chamber of the eye.

Donowitz teaches the ocular implant substantially as claimed, and further teaches a retaining means 46 for holding the inner surface of the implant flush against the inner surface of the eye. Donowitz, however, does not specifically teach that the retaining means comprises an increased diameter.

L'Esperance teaches an ocular drainage tube for draining aqueous humor from the anterior chamber of the eye. The tube comprises anchoring members having increased diameters at both ends (17, 18), thereby ensuring that it may be held snugly against both the inner and outer surfaces of the cornea or sclera. Additionally, the tube comprises a flexible material, such that the anchors may be inserted through the corneal wall. The use of flexible anchoring means having increased diameters is well known in the art of glaucoma shunts because it allows the anchoring means to rest directly against and form to the shape of the ocular wall. Therefore, it would have been obvious to one of ordinary skill in the art to modify the glaucoma shunt of Donowitz with the anchor members having flexible, enlarged diameters of L'Esperance in order to provide a well known, alternate means for preventing movement of the shunt with respect to the ocular wall.

5. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz in view of L'Esperance, and further in view of Brown et al. (US 5,743,868).

Donowitz and L'Esperance reasonably suggest an ocular shunt having a pressure-regulating valve substantially as claimed (see rejection above). Donowitz, however, does not specifically teach that the valve operates such that a 10 mmHg pressure differential is maintained. Brown discloses an ocular implant for regulating pressure between the anterior chamber and the exterior of the cornea such that the pressure difference is kept at 10 mmHg, which is considered to be a normal pressure in the anterior chamber (Column 6, Lines 37-44). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the unidirectional pressure control valve of Donowitz and L'Esperance to regulate fluid flow such that a 10 mmHg pressure differential is maintained in order to keep the anterior chamber of the eye at a natural pressure level.

Response to Arguments

6. Applicant's arguments with respect to claims 19-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
12 February 2009